

Remarks

Claims 1-3, 30-33, 62-65, 93-96, and 123-125 are pending in the referenced application.

I. Specification Objection

Applicants thank the Office for the acknowledgment that the official objection to the specification has been withdrawn.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness

Applicants thank the Office for the withdrawal of the rejection of claims 30-33, 62-65, 93-95, and 123-125 under 35 U.S.C. § 112, second paragraph, indefiniteness.

III. Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-3, 30-33, 62-65, 93-96, and 123-125 stand rejected as allegedly failing to comply with the written description requirement because "...[t]he claims are drawn to genus of carboxylic ester hydrolases that are only defined by molecular weight range and the isoelectric point." Office Action mailed September 7, 2006 at 4. However, Applicants respectfully point out that the pending claims are drawn for example to method claims.

The Office acknowledges that the "specification provides description for a single method of isolation, which yields an extract comprising ester hydrolysis activity." *Id.* However, the Office argues that "Applicants have not purified the enzyme to homogeneity and [have not] performed amino acid analysis to elucidate the structure of the instantly claimed products" and "[t]here is no identification of any partial structure that correlates with the ester hydrolysis function." *Id.* Applicants respectfully traverse the Office's written description rejection.

As the Office acknowledges in the Office Action at page 3:

Whether the specification shows that applicant was in possession of the *claimed invention* is not a single, simple determination, but rather is a *factual determination reached by considering a number of factors*. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of

making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.”

M.P.E.P. § 2163(II)(A)(3)(a) (emphasis added).

In the present application, the claimed invention includes, for example, “[a] method for identifying a candidate compound as a suitable pro-drug, comprising: (a) providing the candidate compound... (b) contacting the candidate compound with an extract... and (c) identifying the candidate compound as a suitable pro-drug....” *See, e.g.*, Claim 1. As such, in the present application, Applicants respectfully submit that possession of the claimed methods is the touchstone for satisfaction of the written description requirement.

Indeed, the specification provides sufficient disclosure showing that Applicants were in possession of the claimed methods. For example, Applicants’ specification provides ample disclosure of providing a candidate compound, contacting the candidate compound with an extract, and identifying the candidate compound as a suitable pro-drug.

Moreover, with regard to extracts, for example as recited in the claimed methods, the specification provides ample written description to demonstrate possession of extracts for use in the methods of the present invention. By way of example, the specification refers to a “PMBC enzyme which we designate GS-7340 Ester Hydrolase”. *See, e.g.*, Specification, page 3, line 19. The specification details “[p]urification of the Enzyme(s) responsible for the cleavage of GS-7340....” Specification, page 1690, lines 7-8. In addition, the specification recites extraction of GS-7340 Ester Hydrolase, anion exchange chromatography, hydrophobic interaction chromatography, hydroxyapatite chromatography, high resolution gel filtration chromatography, and an actual purification summary of GS-7340 Ester Hydrolase. *See, e.g.*, Specification at pages 1691-1694.

Furthermore, the specification recites functional characteristics of GS-7340 Ester Hydrolase such as for example ester hydrolase activity and reduced non-specific esterase activity versus alpha naphthyl acetate. *See, e.g.*, Specification at pages 1690-1691, 1694 (Table 1c). Moreover, the specification provides details regarding biochemical characterization of GS-7340 Ester Hydrolase. *See, e.g.*, Specification at pages 1694-1698. For example, the specification

recites determination of isoelectric point, inhibition by multiple serine hydrolase inhibitors, and molecular weight of GS-7340 Ester Hydrolase on gel filtration. *See id.*

Thus, as discussed, the specification provides sufficient disclosure showing that Applicants were in possession of the claimed methods. For example, Applicants' specification provides ample disclosure of providing a candidate compound, contacting the candidate compound with an extract, and identifying the candidate compound as a suitable pro-drug. Moreover, based on the ample disclosure in Applicants' specification, including for example, physical, chemical, and functional properties of GS-7340 Ester Hydrolase and a method of isolating the enzyme, one of ordinary skill in the art would readily appreciate that Applicants had the requisite possession regarding using an extract in the claimed methods to comply with the written description requirement.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-3, 30-33, 62-65, 93-96, and 123-125 on the basis of 35 U.S.C. § 112 first paragraph, written description.

IV. Rejection Under 35 U.S.C. § 102(b)

Claims 1-3 and 96 stand rejected as allegedly anticipated by Eisenberg *et al.* (2001). The Office argues that Applicants have not provided data to support the assertion that Eisenberg *et al.* (2001) is not published more than one year before the filing date of April 26, 2002 of which the instant application claims the benefit.

Applicants respectfully submit that although the Office cited Eisenberg *et al.* (2001) as the basis for a 102(b) rejection, the Office has provided no evidence that Eisenberg *et al.* (2001) was published more than one year before April 26, 2002.

In order to anticipate under 35 U.S.C. § 102(b), a prior art reference must have been published more than one year prior to the date of application for patent in the United States. Applicants claim the benefit of the filing date of April 26, 2002. As such, the publication date of a reference under 35 U.S.C. § 102(b) must be on or before April 25, 2001.

Eisenberg *et al.* (2001) was published in Nucleosides, Nucleotides & Nucleic Acids, 20(4-7), 1091-1098 (2001), where 20 refers to the volume number and 4-7 refers to the issues

contained therein. Issues 4-7 refer to issues from the fourth through the seventh months of the year, namely from April through July. As such, the Office has provided no evidence that the publication of Eisenberg *et al.* in Volume 20 together with issues through and including the July issues came before April 26, 2001. Applicants respectfully await confirmation on the electronic and paper publication dates of Eisenberg *et al.* (2001) as stated by the Examiner in the September 7, 2006 Office Action.

On the basis of the foregoing, Applicants respectfully submit that Eisenberg *et al.* (2001) does not anticipate under 35 U.S.C. § 102(b) and this rejection should be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully request withdrawal of the outstanding rejections and timely allowance of the pending claims. If the Examiner believes that a telephone conference would be useful in resolving any outstanding issues, she is invited to call Applicants' undersigned representative at (202) 942-5325.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'DRM', is written over the typed name of David R. Marsh.

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